K123632
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510(k) Summary

JAN 25 2013

(As Required By 21 CFR 807.92)

This 510(k) Summary for the Spectranetics 0.035" compatible, 2.3mm and 2.5mm TurboElite Atherectomy Catheters is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

Submitter Information

Company name:	Spectranetics Corporation
Company address:	9965 Federal Drive Colorado Springs, CO 80921
Company phone:	(719) 477-2000 (800) 633-0960
Company fax:	(719) 447-2040

Device Identification

Device trade name:	2.3mm and 2.5mm TurboElite 0.035" Atherectomy Catheters
Device common name:	Laser atherectomy catheter
Classification:	Intraluminal Artery Stripper
Device class:	Class II (per 21 CFR 870.4875)
Device code:	MCW
Establishment Registration number:	3007284006

Performance Standards

There are no performance standards applicable to this device.

Device Description

The Turbo-Elite Atherectomy Catheter is a laser atherectomy catheter constructed of multiple optical fibers arranged circumferentially around a guidewire lumen (0.014 and 0.018, presently). Turbo Elite Laser Catheters are available in Over the Wire (OTW) and Rapid Exchange (RX) configurations. The proposed catalog additions are over-the-wire (OTW) 0.035" guidewire compatible with crossing profiles of 2.3mm and 2.5mm.

The laser catheter is connected to the Spectranetics CVX-300 Excimer Laser System by means of an optical coupler and tail-tubing.

The Turbo Elite, OTW catheters include a luer adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the appropriate sized guidewire.

Indication for Use

The Turbo Elite is intended for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.

Substantially Equivalent Device

The Turbo Elite (previously referred to as CLiRpath Excimer Laser Catheter) was originally cleared by the FDA through a Premarket Notification in the US in 2004. Between 2005 and 2007, Spectranetics filed various 510(k) applications to modify features and indications. The most recently cleared 510(k) application (K071227) serves as our predicate for this 510(k) application.

The intended use, intended patient population, and mode of operation are comparable to the predicate device. The materials of construction, packaging, biocompatibility, sterilization, and shelf-life are identical to the predicate device.

Summary of Studies

Spectranetics performed device integrity testing to support the claim that the substantially equivalent to the predicate device. All device integrity tests for the over-the-wire (OTW) 0.035" guidewire compatible 2.3mm and 2.5mm Turbo Elite Atherectomy Catheters met the specified requirements, which consisted of:

- Visual Inspection and Dimensional Testing
- *In vitro* Liquid Leak Pressure Testing
- *Tensile Strength*
- *In vitro Track Testing*
- Laser testing
- Accelerated age testing

Conclusion

Numerous similarities support a determination of substantial equivalence of the 0.035" compatible 2.3mm and 2.5mm Turbo Elite to the currently cleared 0.018" compatible 2.3mm and 2.5mm TurboElite devices. Based on data and information presented, it can be concluded that the 0.035" compatible 2.3mm and 2.5mm Turbo Elite Laser Atherectomy Catheters are as safe, as effective, and perform substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2013

Spectranetics Corp.
c/o Ms. Christine Godleski
Senior Regulatory Affairs Specialist
9665 Federal Drive
Colorado Springs, CO 80921

Re: K123632
Trade/Device Name: 2.3mm and 2.5mm Turbo Elite 0.035" Atherectomy Catheters
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW
Dated: November 15, 2012
Received: November 23, 2012

Dear Ms. Godleski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K123632

Indications for Use

510(k) Number (if known): TBD
Device Name: Turbo Elite 035
Indications For Use:

The Turbo Elite is intended for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123632